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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,736	07/21/2003	Masahiro Okuda	Q76592	2795

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EXAMINER	
HANLEY, SUSAN MARIE	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,736	OKUDA, MASAHIRO	
	Examiner	Art Unit	
	Susan Hanley	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *22 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The initial response containing an amendment and remarks filed 8/29/06 and the supplemental remarks and amendment are acknowledged.

Claims 1-23 are presented for examination.

Election/Restrictions

Newly submitted claims 22 and 23 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly added claims 22 and 23 are drawn to a method for detecting lupus anticoagulant in blood while claims 1-21 are directed to a reagent compostion. The two groups are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the phospholipids can be used to measure coagulation times tht are unrelated to lupus conditions.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 22 and 23 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-21 are under examination.

Claim Rejections - 35 USC § 102

Claims 1, 4, 6-14, and 19-21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Brown (US 5,314,695) in light of Webster's Dictionary.

Claims 1-6 and 8-13 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Smirnov et al. (1999; "Smirnov") in light of Webster's Dictionary.

Applicant summarizes the reagent kit of the instant invention and asserts that it has an advantage of discriminating LA-positive patients from individuals having other anticoagulant diseases. Applicant argues that the reference by the Office action that Brown is related to "testing APTT coagulation times" is incorrect. Applicant asserts that Brown discloses a coagulation time reagent containing phospholipids including phosphatidylserine and tht Brown teaches the measurement of prothrombin times with various ratios of the PS content to the total content of phospholipids. Regarding Smirnov, Applicant asserts that Smirnov related to phospholipids vesicles having various concentrations of PS for determining the optional concentration of PL for prothrombin activation and factor Va inactivation. Applicant alleges that both Brown and Smirnov are silent as to measuring coagulation time of blood containing LA. Applicant asserts that Brown does not teach or suggest that a combination of two reagents having different PS content ratios from each other may show the absence of LA. Applicant concludes that neither Brown nor Smirnov disclose a reagent kit or a method for detecting LA.

Responding to Applicant's assertion that the instant invention is advantageous for discriminating LA-positive patients compared to other anticoagulant diseases, this statement amounts to an allegation of patentability without factual support. Responding to Applicant's assertion that the Offices statement that Brown is related to "testing APTT coagulation times" is incorrect, it is unclear what this statement has to do with overcoming the rejection or even why the observation was made. In response to applicant's argument that Brown and Smirnov are silent as to measuring coagulation time of blood containing LA and that Brown does not teach or suggest that a combination of two reagents having different PS content ratios from each other may show the absence of LA, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The claims are drawn to a reagent kit comprising phospholipids in various amounts and ratios. Both Brown and Smirnov teach the claimed reagents. Hence, the prior art reagents are capable of the intended use.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, and 6-21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US 5,314,695) and Webster's Dictionary in light of Rosen et al. (US 6,395,501; "Rosen").

Applicant states that he/she disagrees with the view set forth by the Office. Applicant argues that it would not be obvious to the ordinary artisan to make and use the inventive reagent because Brown and Rosen fail to disclose a reagent kit for detecting LA.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. Applicant has not discussed by there is disagreement with the position set forth by the Office.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Russell's venom, ellagic acid, kaolin or silica derivatives for tissue factor in the phospholipid compostion taught by Brown because the various reagents are all recognized as activators of the coagulation pathway and have been used with phospholipids to measure anticoagulant activity. The ordinary artisan would have had a reasonable

expectation that he or she could employ Russell's venom, ellagic acid, kaolin or silica derivatives in place of tissue factor as activators because Russell's venom, ellagic acid, kaolin or silica derivatives have been shown to activate the coagulant pathway for the purpose of measuring anticoagulant activity.

In response to applicant's argument that neither Brown nor Rosen teach the measurement of coagulation time of blood containing LA, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The claims are drawn to a reagent kit comprising phospholipids in various amounts and ratios. Brown teaches the claimed reagents. Hence, the prior art reagents are capable of the intended use.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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